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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,806	07/11/2001	Avi Ashkenazi	10466/40	1365

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EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/903,806	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *39-43*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

David S Romeo
Primary Examiner
Art Unit: 1647

Continuation of 5. does NOT place the application in condition for allowance because: It is acknowledged that Applicant relies upon PCT/US98/18824 filed 09/10/1998 for the effective filing date of 09/10/1998. Insofar as the gene amplification data disclosed in example 92 and table 8 of the present application, that was first disclosed in application serial no. 60/099,803 (filed September 10, 1998), was also disclosed in PCT/US98/18824 (filed September 10, 1998), then Applicant is entitled to the benefit of the filing date of the PCT/US98/18824 application for the specific PRO214 polynucleotide (SEQ ID NO: 108).

Applicant argues that the results of the gene amplification assay provide specific and substantial utility for the presently claimed antibodies. Applicant argues that that a prima facie case of lack of utility has not been established because the evidence relied upon by the examiner does not establish that it is more likely than not, in general, that a correlation exist between gene amplification and mRNA/protein expression. Applicant's arguments have been fully considered but they are not persuasive. The fact remains that no information is provided in the gene amplification data regarding level of expression, activity, or role in cancer of the PRO214 polypeptide. The fact remains that the evidence relied upon by the examiner indicates that DNA amplification is not always associated with overexpression of the gene product. Consequently, the asserted diagnostic utility of the PRO214 polypeptide requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use, and the increased copy number of PRO214 DNA does not provide a readily apparent use for the PRO214 polypeptide, for which there is no information regarding level of expression, activity, or role in cancer. The examiner is not saying that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. The examiner is saying that the asserted diagnostic utility of the PRO214 polypeptide requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use.

Applicant argues that a polypeptide encoded by a gene that is amplified in cancer would still have a specific and substantial utility, as evidenced by the declaration of Avi Ashkenazi. However, the declaration of Avi Ashkenazi is not of record in the present application and the examiner cannot comment on evidence that is not of record. To the extent that Applicant paraphrases the declaration of Avi Ashkenazi, Applicant's arguments have been fully considered but they are not persuasive because further research would still have to carried out in order to identify or reasonably confirm a "real world" context of use, and no information is provided in the gene amplification data regarding level of expression, activity, or role in cancer of the PRO214 polypeptide.

The examiner accordingly finds that the gene amplification data disclosed in example 92 and table 8 of the present application, which was first disclosed in PCT/US98/18824 filed 09/10/1998, does not satisfy the utility requirement of 35 U.S.C. ' 101 for the polypeptide. Hence, the gene amplification data does not satisfy the how to use requirement of 35 U.S.C. ' 112, first paragraph, for the polypeptide. The gene amplification data does not satisfy the utility requirement of 35 U.S.C. ' 101 and the how to use requirement of 35 U.S.C. ' 112, first paragraph, for the claimed antibody for the same reasons that the gene amplification data does not satisfy these requirements for the polypeptide. Other activities of the polypeptide are disclosed in the present application. The claims have not been rejected under 35 U.S.C. ' 101, utility, and 35 U.S.C. ' 112, first paragraph, in view of these other disclosed activities of the polypeptide. Although the present application enables the specific PRO polypeptide, neither the polypeptide nor the claimed antibodies obtain the benefit of the earlier filing date of the application in which the gene amplification data is disclosed because in order to obtain the benefit of an earlier filing date in the United States under 35 U.S.C. 120 an invention must disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States. Accordingly, the claimed subject matter has an effective filing date of February 22, 2000.

Claim Rejections - 35 USC § 102:
Claims 39-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Ruben (n11). Applicant argues that Ruben is not prior art under 102(b). Applicant's arguments have been fully considered but they are not persuasive. The claimed subject matter has an effective filing date of February 22, 2000, as discussed above.

Claim Rejections - 35 USC § 103:
Claims 39, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koehrer (u11). Applicant argues that Koehrer is not prior art. Applicant's arguments have been fully considered but they are not persuasive. The claimed subject matter has an effective filing date of February 22, 2000, as discussed above.

Claim Rejections - 35 USC § 112:
Claim 39 is indefinite because it recites the term "specifically binds". Applicant argues that the art recognizes that an antibody that specifically binds a particular antigen does not significantly cross-react with another antigen. Applicant's arguments have been fully considered but they are not persuasive. If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph is appropriate. The test for definiteness under 35 U.S.C. 112, second paragraph is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "specifically binds" an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth. .